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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Dr. Martin	Lenhardt	Richmond, Va.
Dr. Kevin	Ward	Richmond, Va.

☐ Additional inventors are being named on the ____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

INTRAOCULAR AND INTRACRANIAL PRESSURE MONITOR

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☒ Customer Number 30743 → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

☒ Firm or Individual Name	Whitham, Curtis & Christofferson P.C.
Address	Michael E. Whitham
Address	11491 Sunset Hills Road/ Suite 340
City	Reston · State Va. · ZIP 20190
Country	U.S.A. · Telephone 703-787-9400 · Fax 703-787-7557

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 2
☒ Drawing(s) *Number of Sheets* 12
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.
☒ A check or money order is enclosed to cover the filing fees
☒ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number 50-2041
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____

Respectfully submitted,

SIGNATURE [signature]

Date 8-8-03

TYPED or PRINTED NAME Michael E. Whitham

REGISTRATION NO. *(if appropriate)* 32,635

TELEPHONE 703-787-9400

Docket Number: 02940323PR

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

INTRAOCULAR AND INTRACRANIAL PRESSURE MONITOR

Pressure increase in the brain, contained in the skull, is a serious medical condition that can be life threatening. Intracranial pressure changes can be detected non invasively using acoustic stimulation and analysis. The brain and the skull are coupled resonant systems that will respond in a predictable fashion to pressure increases given the bioboundary conditions. Changes in acoustic damping are correlated with changes in cerebral spinal fluid (CSF) or intracranial pressure (ICP).

There are two "windows" to the interior brain pressure, the ear and the eye. Ear monitoring of changes in CSF pressure have been attempted (Marchbands, 1999), but have not resulted in a feasible clinical device. Direct measures of the skull vibration or using ultrasonic probes have also been attempted with some success. The later is technically complicated, and is not a promising clinical alternative. Eye pressure does correlate with CSF and various approaches have been used since eye pressure assessment is a common opthamological procedure. Two types of intraoccular pressure measurement have been reported which have various correlations with ICP. These include noncontact air tonometry which measures intraoccular pressure (Sheeran 2000, Salman 1997). This technique has produced conflicting results and at best could likely only provide a rough estimate of ICP. The other technique reported is opthalmodynamometry which is an applanation technique (Draeger 1999, Draeger 2000). This technique applies pressure to the cornea and measures the intraoccular arterial pulse wave. Pressure is applied to the corneal surface until the intraoccular arterial pulse wave (produced by the ophthalmic artery) is

obliterated. The pressure at which this happens has been termed intracranial arterial pressure and some have used this pressure to infer changes in ICP. However, this measure cannot be equated with ICP.

The present invention capitalizes on the acoustic resonant prosperities of the eye, a globe that can be modeled accurately as a sphere. Sixty percent of the globe is bounded by bone, representing a high impedance interface. Calculations of resonant frequencies range from approximately 95 -140 kHz. Ultrasonic resonance is expected given the small radius of the eye (~0.75 mm). While not wanting to be limited by initial calculations and relatively few direct measurements, we intend to sweep tones from well below and well above projected resonant frequency. Various anatomical features and less than sphere geometry make exact predictions difficult. Nonetheless a wide range of frequency sweeping to ensure resonant frequencies will be covered is selected as a prudent tactic.

Thus as the pressure is increased on the globe, intraocular pressure will rise. Increases in IOP will increase the acoustic damping. Increased damping will be reflected in a reduction in intensity of the signal recorded at both sensors place comfortably over the closed eyelid.

The sensors will be constructed of piezoelectric film, coated with Mylar. Half the sensor will receive the vibrations of the eye and the second half will be a driving actuator. Alternatively a driving actuator can be placed any where on the skin of the head.

Algorithms have been developed to compare the signals between the eyes and compute an equivalents intracranial pressure. Exact calibration remains to be performed.

Additional value using this technique to measure ICP may lie with its use in conjunction with transcranial acoustical measurements. In this manner, changes in an acoustical signal generated at the eye may be measured transcranially or transcranially produced acoustical signals could be measured at the eye with the above system. Thus as ICP changes, the acoustical signals generated across these points will be changed. Furthermore, the ability to bilaterally measure the signals using both eyes may assist in confirming measures. Alternatively, the potential may exists to allow detection of hemispheric location of large accumulations of intracranial blood after trauma such as epidural and subdural hematomas.

3. What is novel or unusual about this invention? How does it differ from present technology? What are its advantages?

non invasive acoustical comfortable monitor

4. What is the closest technology currently available, upon which this invention improves?

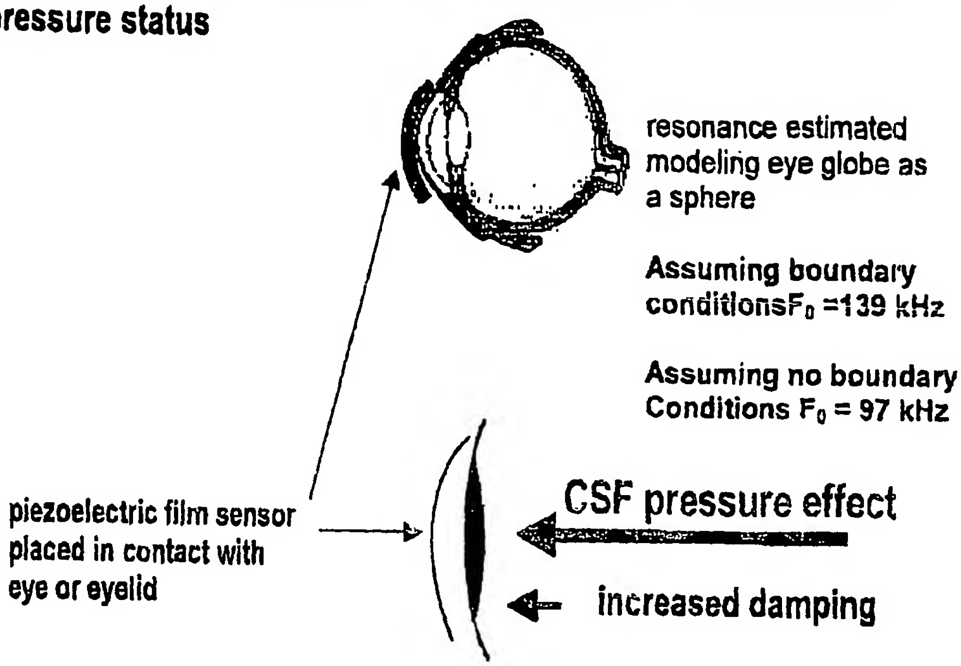
air tonometry, ophthalmodynamometry

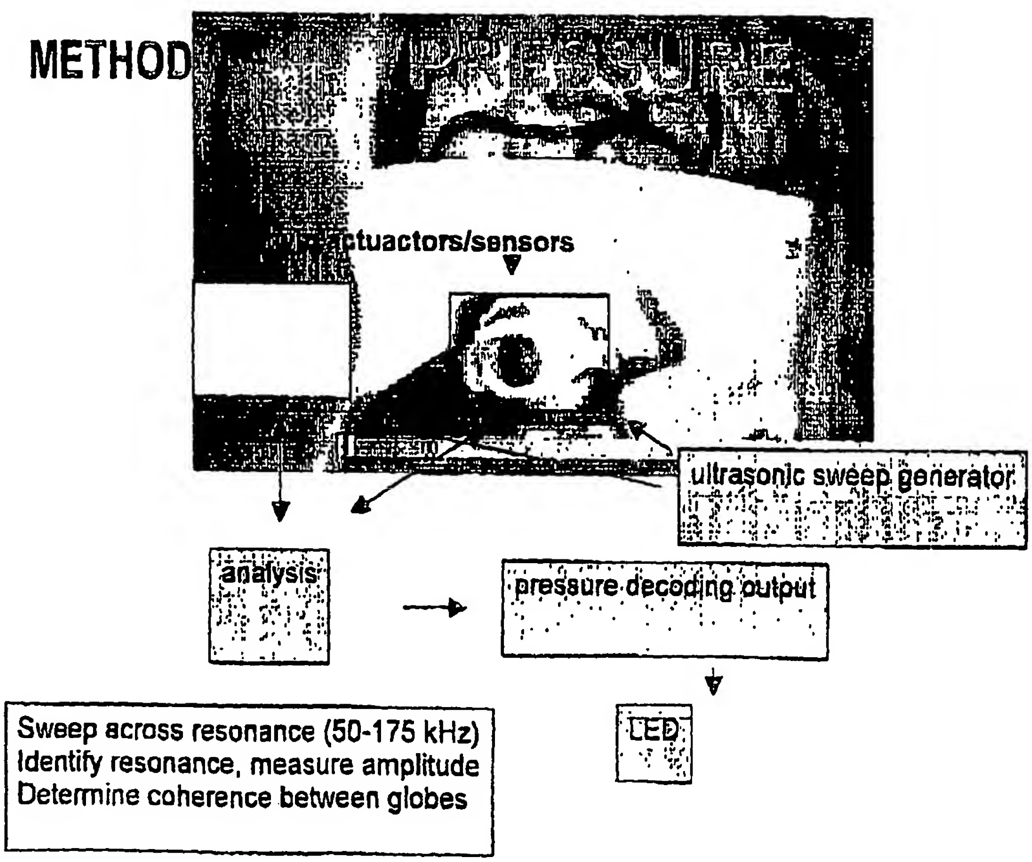
6. What uses do you foresee for the invention, both now and in the future?

broad application in emergency medicine, critical care medicine, trauma surgery, neurology, neurosurgery and internal medicine, military medicine, aviation/space medicine

An increase in brain pressure, if ~~goes~~ undetected and untreated, is potentially fatal. Brain pressure can be monitored by acoustic eye patches which are confortable, accurate and provide a rapid and sensitive reading.

eye resonance pressure effect as an indicator of cerebral fluid pressure status

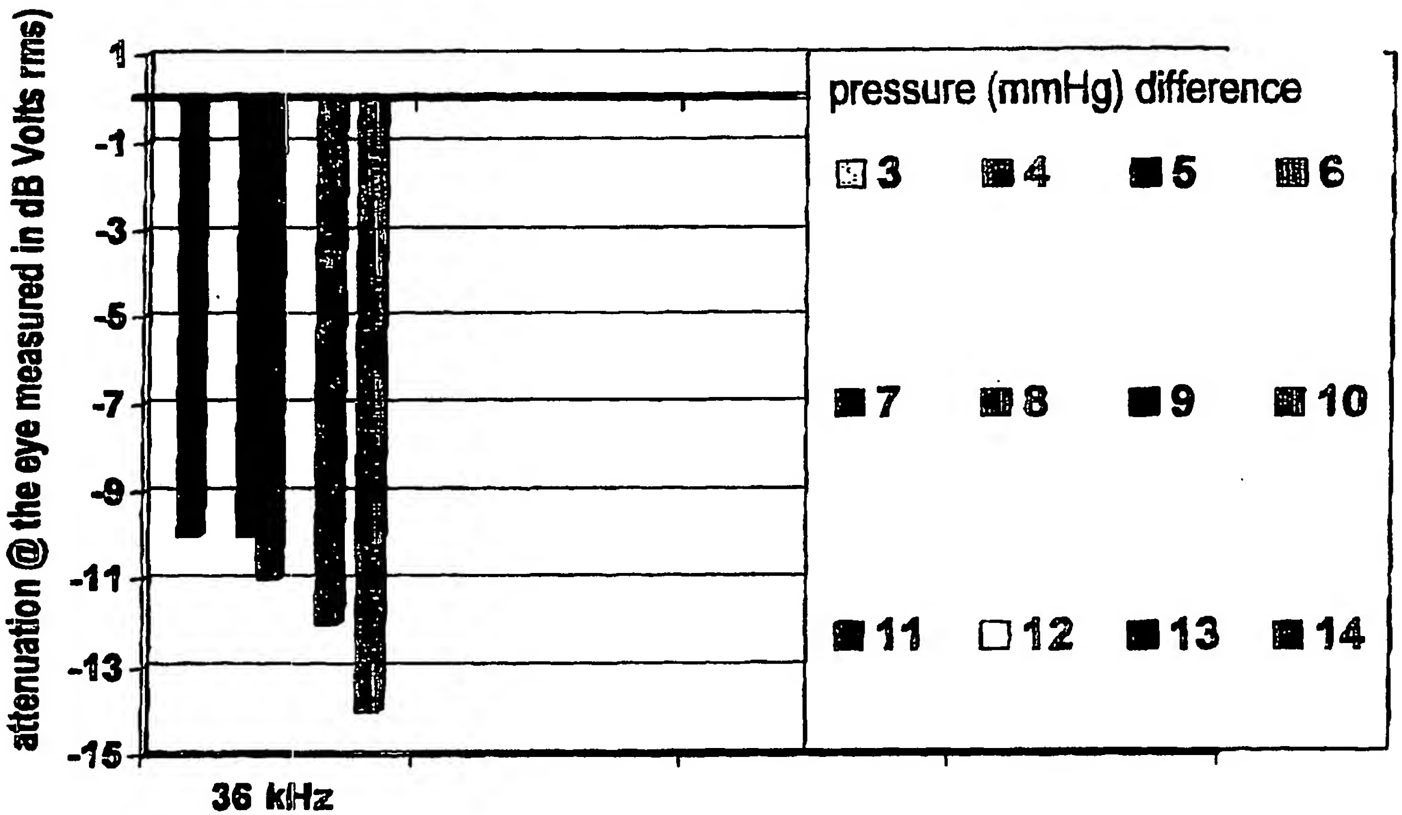




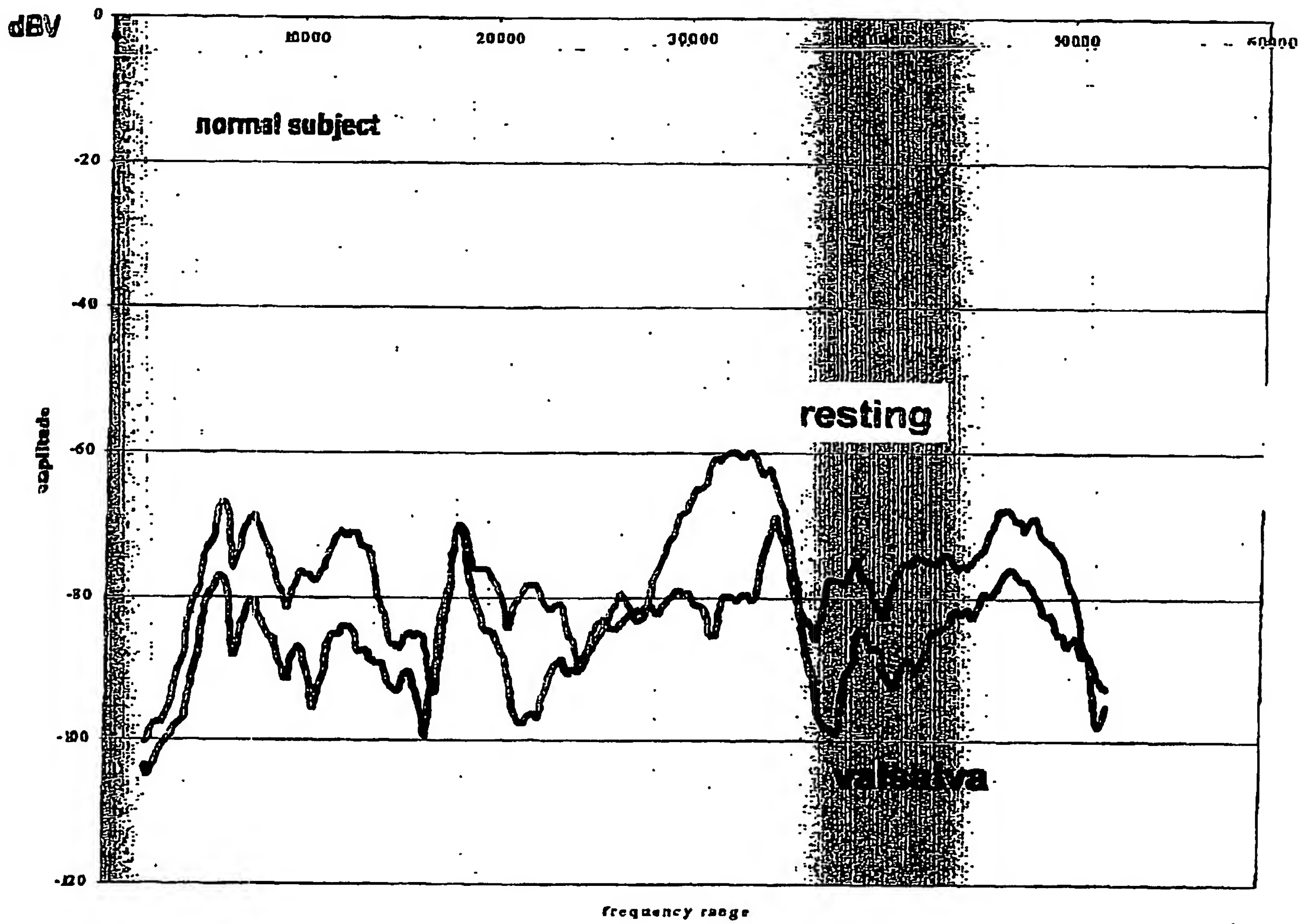
Data from five subjects are presented in which recording from the eye, in response to head vibration, reveals the pattern of decreased acoustic transmission (damping) with increasing ICP. This relationship is graphically displayed in the first figure.

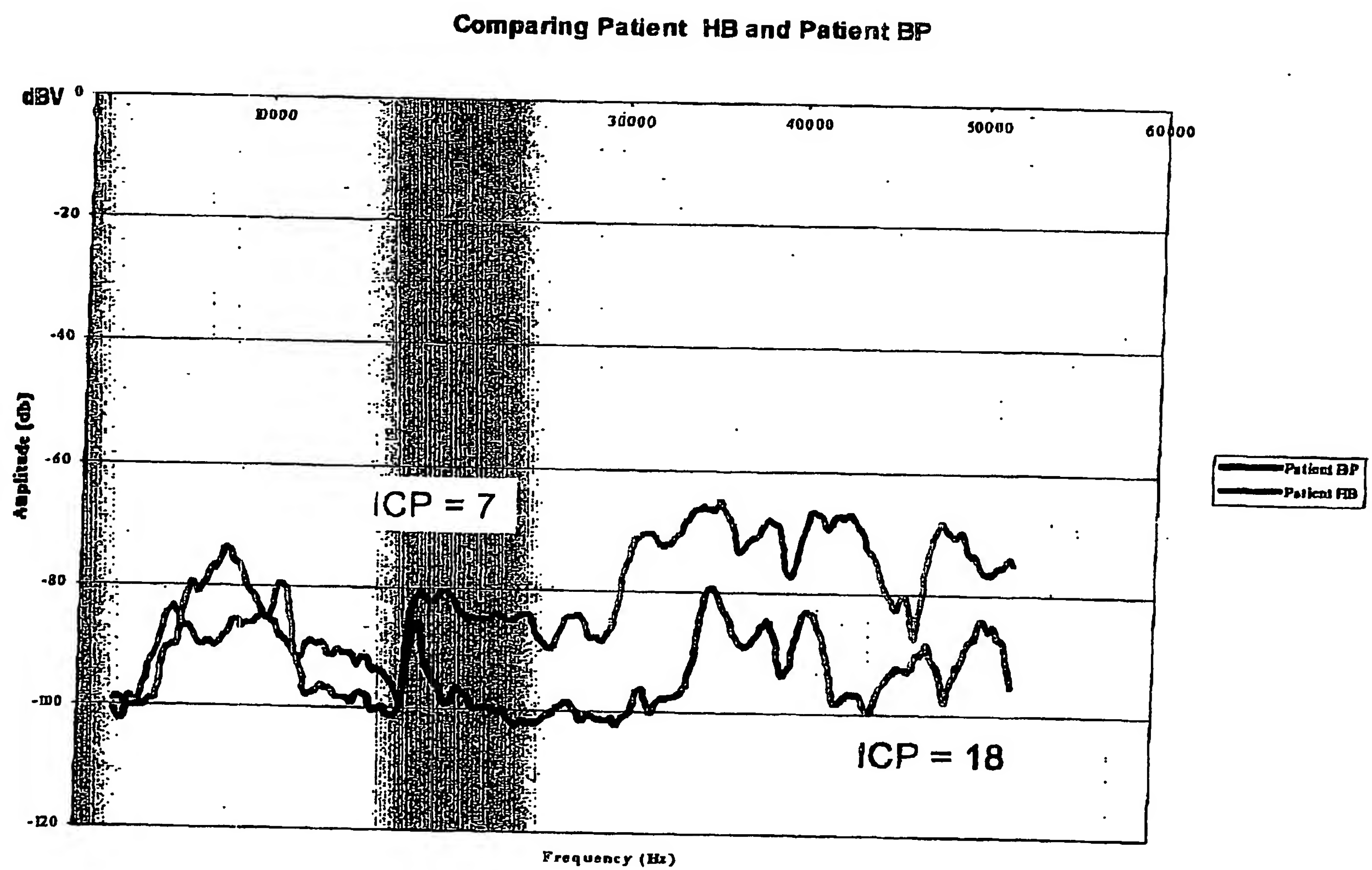
Patient Initials	Invasive Method Monitoring	ICP
HB	Ventriculostomy	7 mm Hg.
GC	Ventriculostomy	11 mm Hg.
GJ	Ventriculostomy	15 mm Hg.
RR	Ventriculostomy	20 mm Hg.
BP	Ventriculostomy	18 mm Hg.

Attenuation (dBV_{rms}) with ICP increase with eye recording

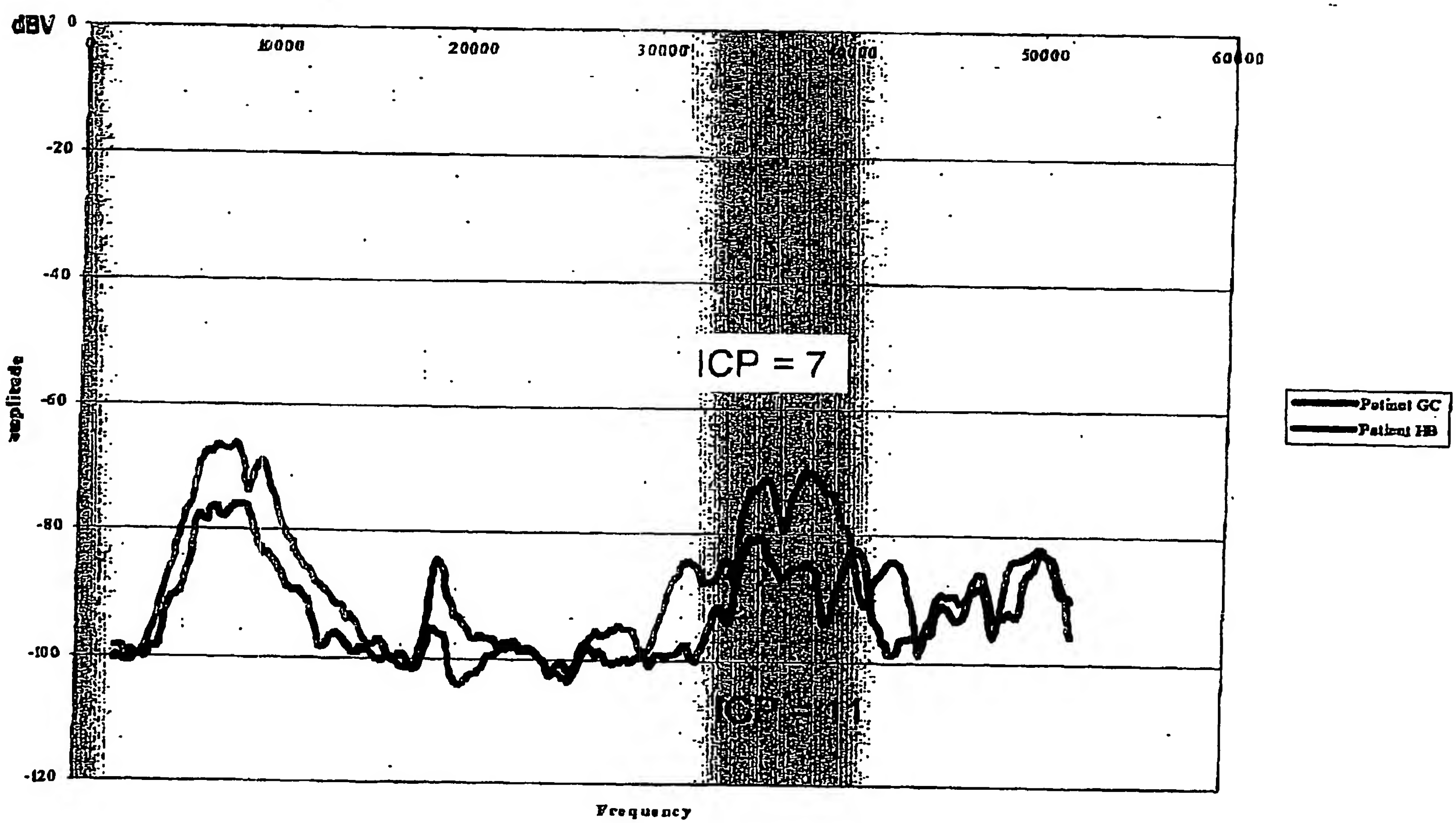


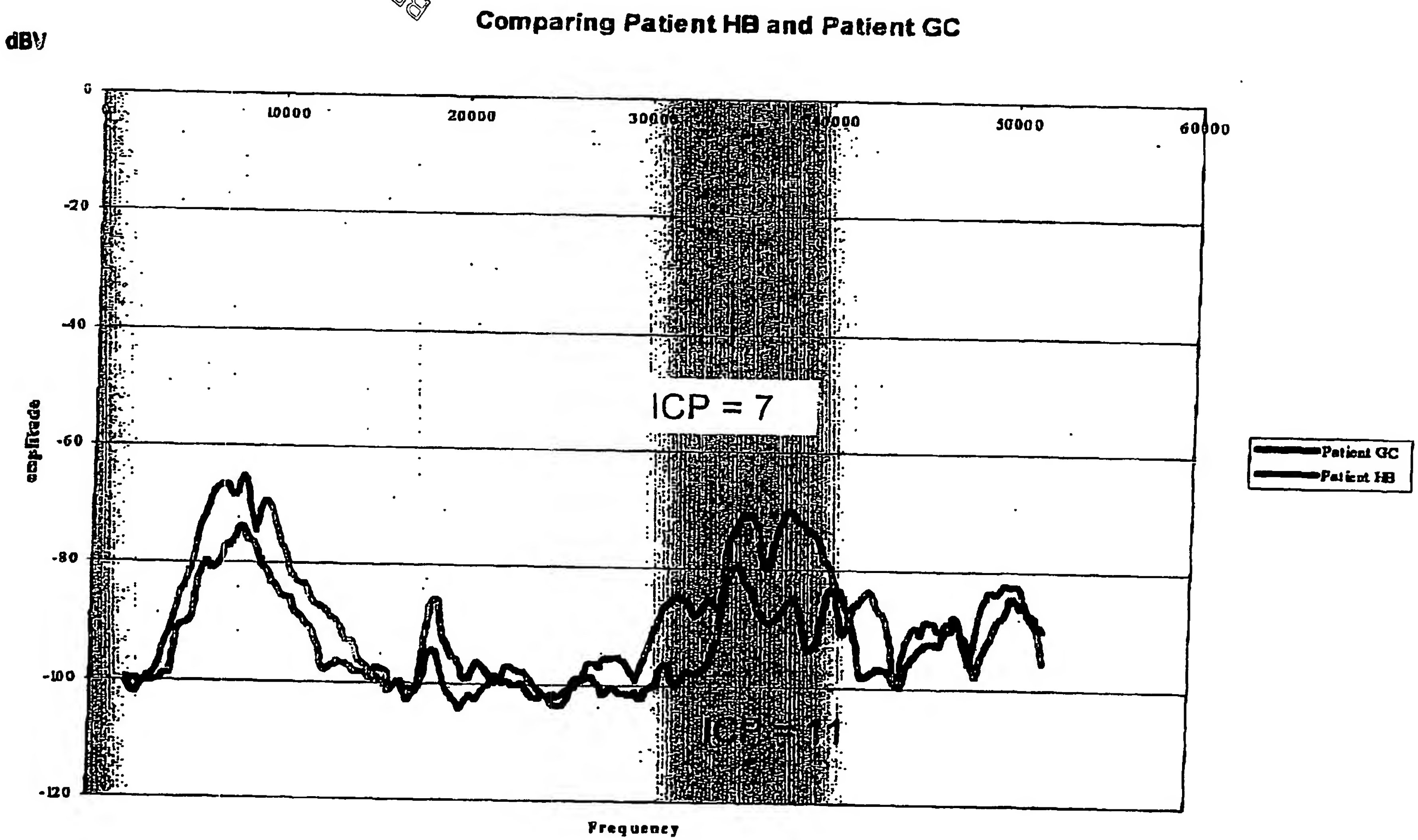
eye valsalva reading versus normal

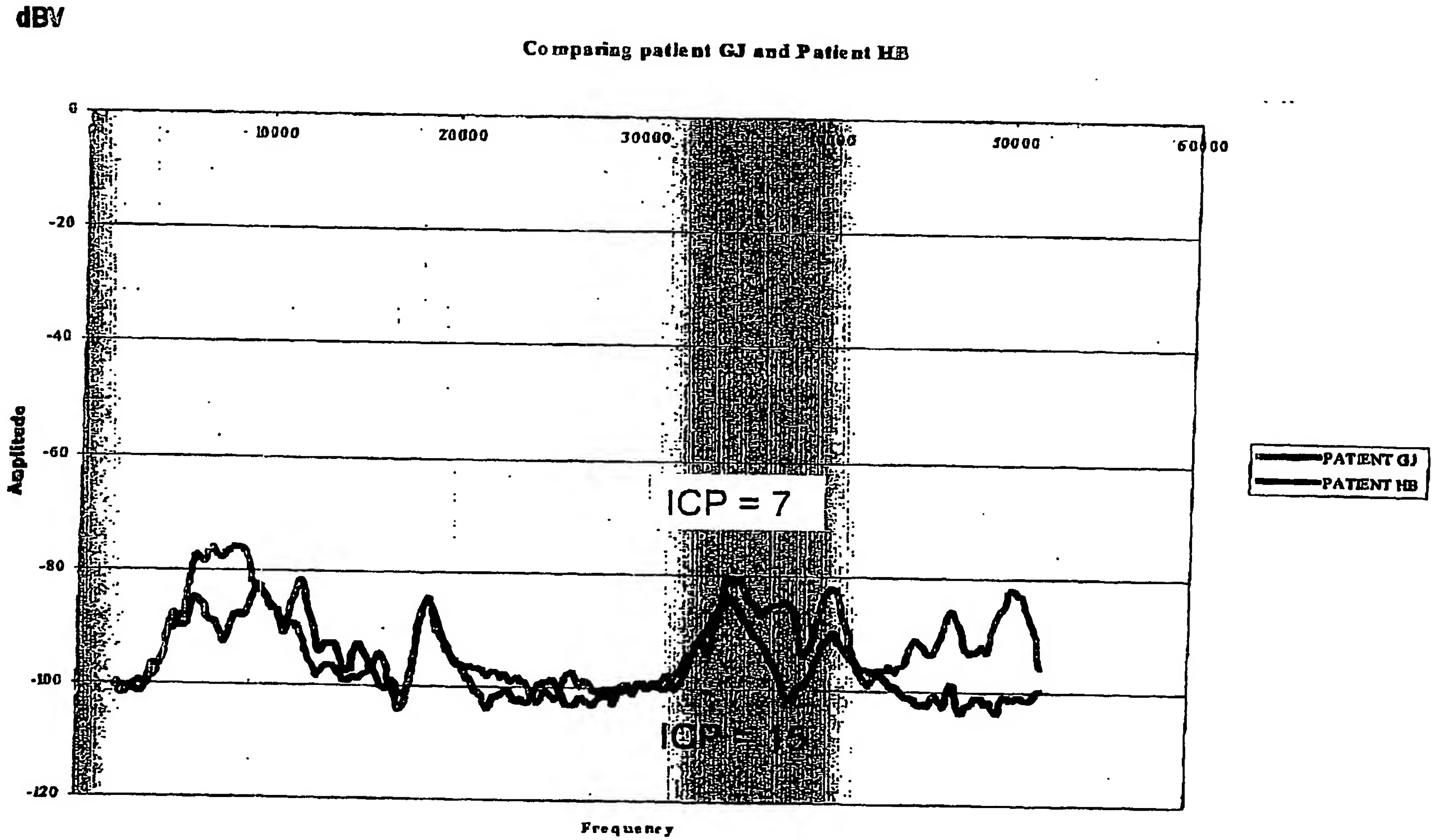


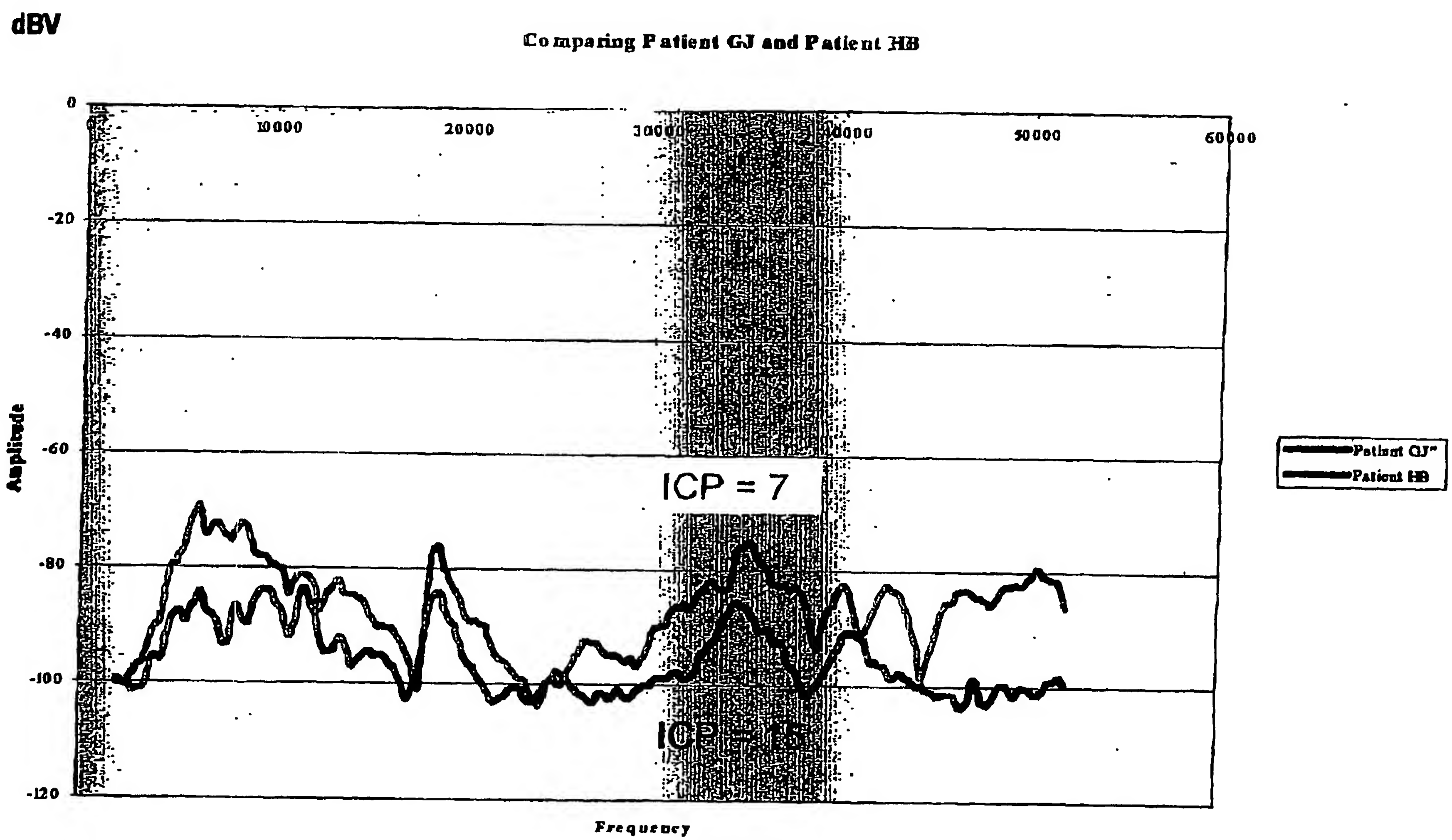

Comparing Patient HB and Patient BP
dBV
0
-20
-40
-60
-80
-100
-120
Amplitude (db)
10000
30000
40000
50000
60000
Frequency (Hz)
Patient BP
Patient HB
ICP = 7
ICP = 18

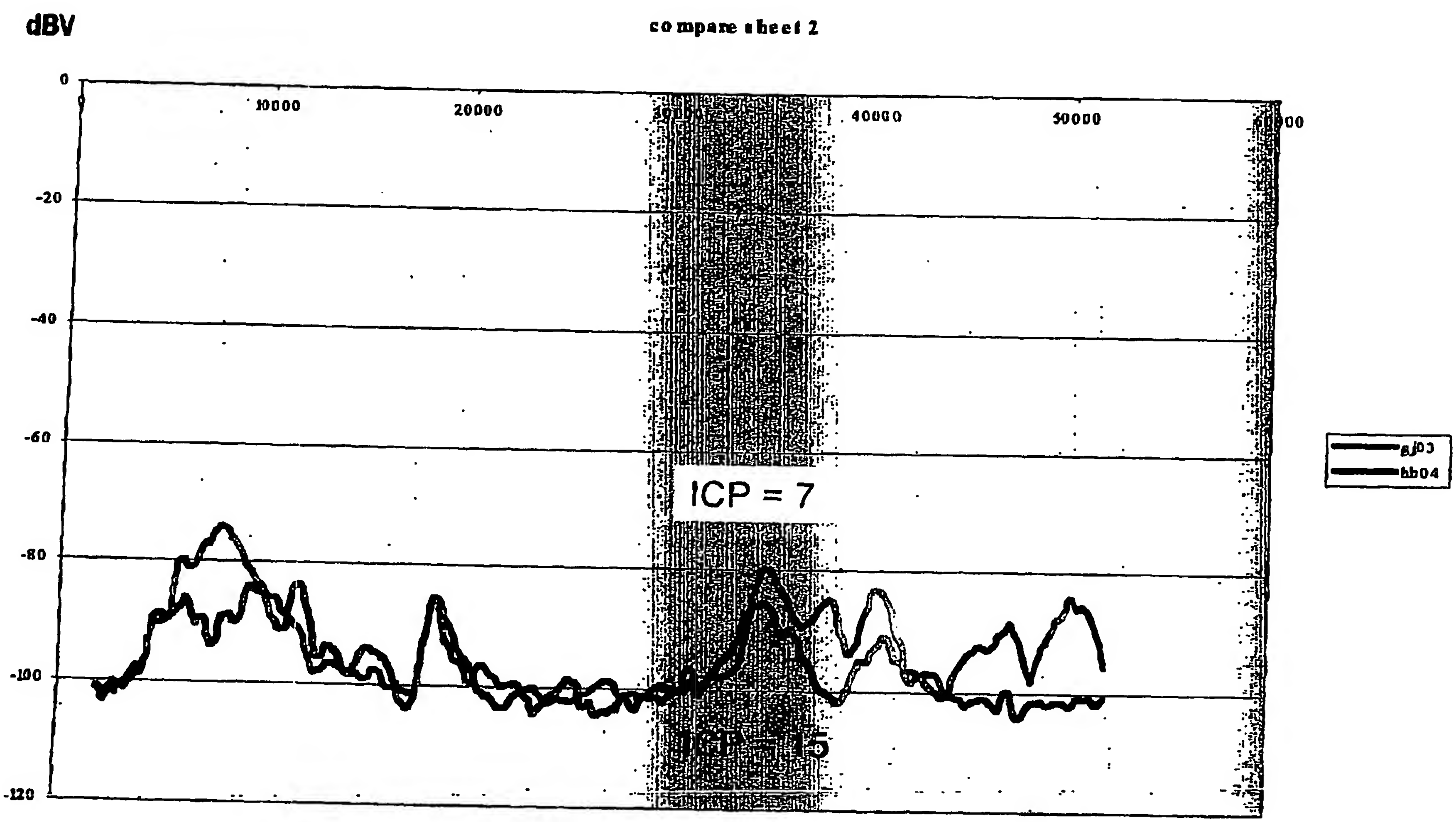
Comparing Patient HB and GC




Comparing Patient HB and Patient GC
dBV
amplitude
0
-20
-40
-60
-80
-100
-120
10000
20000
30000
40000
50000
60000
Frequency
ICP = 7
ICP = 11
Patient GC
Patient HB

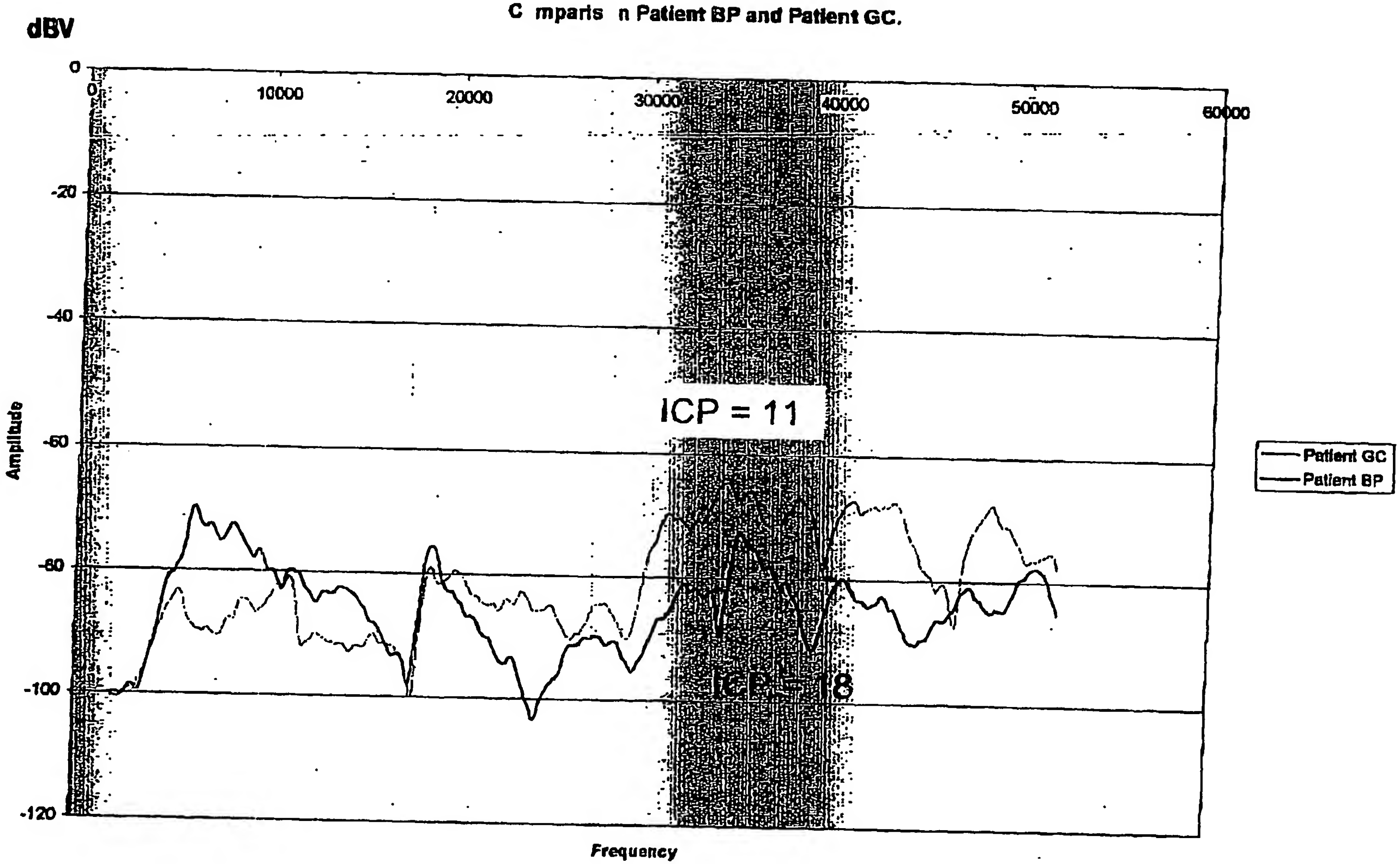

dBV
Comparing patient GJ and Patient HB
Amplitude
0
-20
-40
-60
-80
-100
-120
10000
20000
30000
50000
60000
Frequency
ICP = 7
PATIENT GJ
PATIENT HB

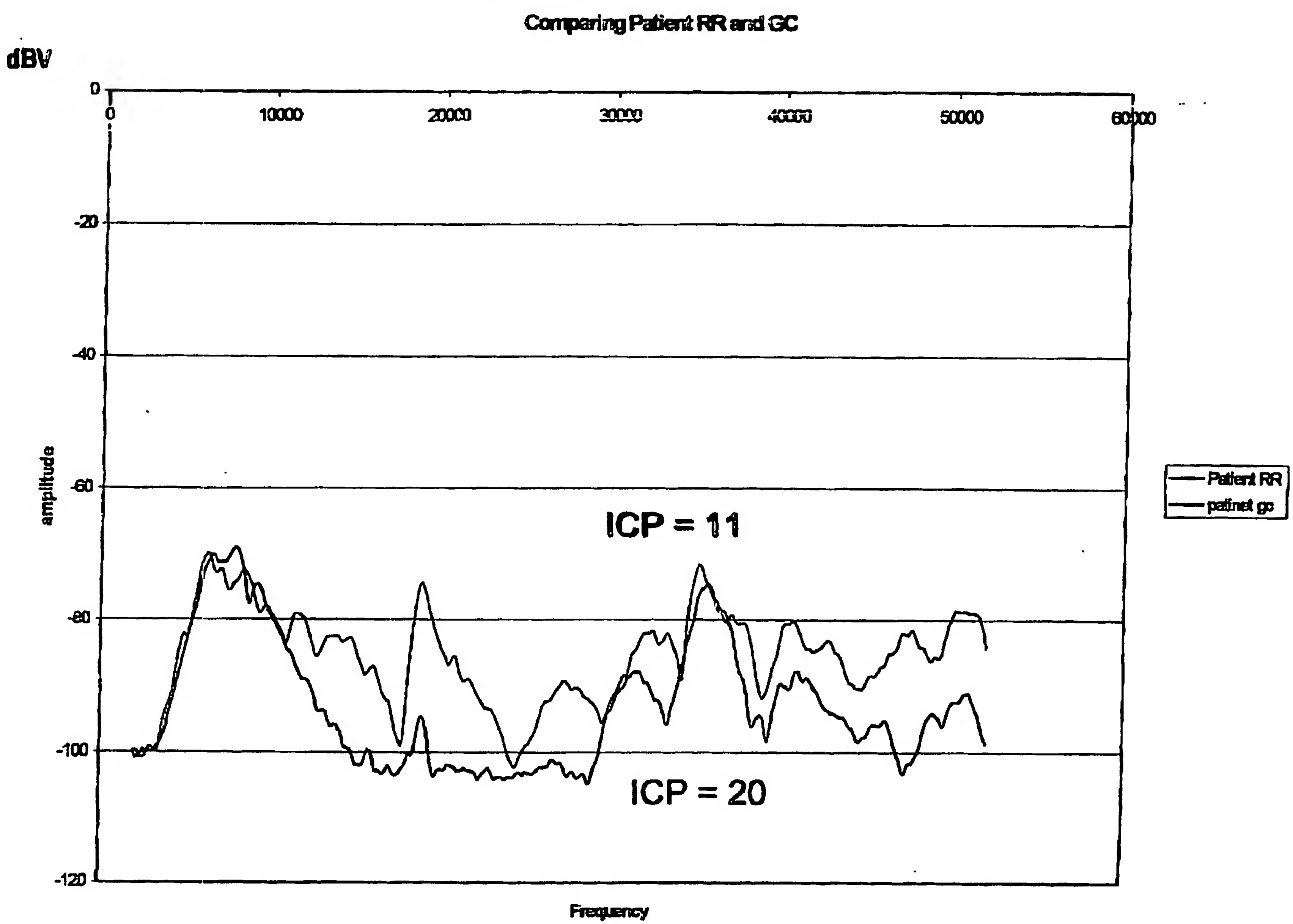

dBV
Comparing Patient GJ and Patient HB
0
-20
-40
-60
-80
-100
-120
Amplitude
10000
20000
30000
40000
50000
60000
Frequency
ICP = 7
Patient GJ"
Patient HB



dBV
compare sheet 2
0
-20
-40
-60
-80
-100
-120
10000
20000
30000
40000
50000
60000
ICP = 7
ICP = 15
gj03
hb04

C mparis n Patient BP and Patient GC.




Comparing Patient RR and GC
dBV
amplitude
0
-20
-40
-60
-80
-100
-120
0
10000
20000
30000
40000
50000
60000
Frequency
ICP = 11
ICP = 20
Patient RR
patinet gc